JUL 15 2003

K031207

VII. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

Submitter Information:

Casey Surgical, LLC
17722 Loop Road
Holt, MO 64048

Contact Person: Kevin Casey

Phone: 816-739-9959

Date Prepared: April 14, 2003

Device Information:

Proprietary Name: Safety Release ™ Arch Bar Kit

Common Name: Intermaxillary Fixation System

Classification Name: Intraoral ligature and wire lock

Predicate Devices: **Synthes Quick Lock™ K991004**
Unisplint K820944

Device Description: The Casey Surgical Safety Release ™ Arch Bar Kit is made of four components which are installed by an oral surgeon or dentist along with ligature wires. The installed device provides temporary jaw immobilization. The device incorporates a safety release mechanism.

Intended Use: Casey Surgical Safety Release ™ Arch Bar Kit is indicated for use in intermaxillary and maxillo-mandibular fixation.

Comparison of Technical Characteristics to Predicate Device: Similar to predicate devices K991004 Synthes Quick Lock™ IMF system and K8200944 Dental Arch Bar in materials of construction and indications for use. The Casey Surgical Safety Release ™ Arch Bar Kit has the additional safety release feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

Casey Surgical, LLC
C/O Mr. James Stanley
Associate Director of Compliance & Medical Devices
Regulatory Clinical Consultants, Incorporated
200 NE Mulberry, Suite 200
Lee's Summit, Missouri 64086

Re: K031207
Trade/Device Name: Casey Surgical Safety Release™ Arch Bar Kit
Regulation Number: 21 CFR 872.4600
Regulation Name: Intraoral Ligature and Wire Lock
Regulatory Class: II
Product Code: DYX
Dated: April 14, 2003
Received: April 23, 2003

Dear Mr. Stanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031207

I. Indications for Use

510(k) Number (if known): K031207

Device Name: Casey Surgical Safety Release ™ Arch Bar Kit

Indications for Use: Casey Surgical Safety Release ™ Arch Bar Kit is indicated for use in intermaxillary and maxillo-mandibular fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031207